

REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on April 14, 2009. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-201 on the account statement.

Claims 8-20 are pending in this application. Claims 1-7 and 21-35 were previously withdrawn. In the Office Action, Claims 8, 14-16 and 18 are rejected under 35 U.S.C. §102 and Claims 8-13, 16, 17, 19 and 20 are rejected under 35 U.S.C. §103. In response, Claims 8 and 16 have been amended. The amendments do not add any new matter and are supported in Applicants' specification, for example, at page 9, lines 12-13. In view of the amendments and for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 8, 14-16 and 18 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,162,177 to Stupak et al. ("*Stupak*"). Independent Claim 8 and 16 have been amended to recite, in part, a product comprising a chewable tableted center, wherein the chewable tableted center is not a chewing gum, and a coating comprising a medicament. Applicants believe this rejection is improper and respectfully traverses it for at least the reasons set forth below.

The present invention provides, for example, a coated tablet product that rapidly absorbs into the body due to absorption of a medicament through the oral mucosa as the coated tablet is chewed. See, Applicants' specification, page 6, lines 17-24. This rapid absorption occurs through continual chewing of the product to create fluid pressure, which causes the medicament to enter the systemic system of the chewer through the oral mucosa contained in the buccal cavity. *Id.*

By contrast, Applicants submit that *Stupak* fails to disclose or suggest a product comprising a chewable tableted center, wherein the chewable tableted center is not a chewing gum, and a coating comprising a medicament as required, in part, by independent Claims 8 and 16. Instead, *Stupak* teaches a dosage form comprising a core having a medicament, an enteric coating surrounding the core, and an immediate release coating applied over the enteric coating, the immediate release coating applied as a dusting powder over the enteric coating. See, *Stupak*, column 1, lines 45-57 and column 3, lines 3-9. This dosage form is intended for swallowing

rather than chewing, as is evident from the use of the enteric coating. Enteric coating, which breaks down slowly in the digestive tract to allow prolonged delivery of medicament in the core, would simply break apart if chewed, thereby preventing its intended use for release in the digestive tract. See, *Stupak*, column 1, lines 53-55 and column 2, lines 50-61. In fact, if the enteric coating had structure sufficient to resist breaking when chewed, then the core would inherently not be chewable, as the core would be inaccessible during chewing due to the break-resistant coating. Moreover, due to the absence of sweeteners or masking flavors in the core to mask any bitterness or undesirable flavor of the medicament, it is clear that the *Stupak* composition core was not intended for chewing and, instead, was intended for decomposing in the digestive tract. Therefore, because of the composition of the core, the existence of an enteric coating, and the teachings of intended use of the dosage form in *Stupak*, Applicants again submit that *Stupak* fails to disclose or suggest a product with a chewable tableted center.

Accordingly, Applicants respectfully request that the anticipation rejection with respect to Claims 8, 14-16 and 18 be reconsidered and the rejection be withdrawn.

In the Office Action, Claims 8, 10-13, 16, 19 and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Stupak* in view of U.S. Patent No. 6,060,078 to Lee ("*Lee*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Applicants submit that the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims. As stated above, *Stupak* fails to disclose or suggest a product comprising a chewable tableted center, wherein the chewable tableted center is not a chewing gum, and a coating comprising a medicament as required, in part, by independent Claims 8 and 16. *Lee* fails to remedy the deficiencies of *Stupak*, as the Office Action relies on *Lee* arguably to disclose taste masking agents rather than for teaching chewable characteristics of a core surrounded by a coating.

Applicants also submit that the cited references are not combinable because *Lee* teaches away from *Stupak*. *Stupak* teaches that a method for manufacturing the core for the tablet of the invention involves forming a solid dispersion by "melting the carrier material and dissolving the flutamide in the melted carrier material" (emphasis added). See, *Stupak*, column 3, lines 19-22. *Stupak's* Examples 1 and 2 likewise teach that preparation of a tablet core requires a solid dispersion prepared by "melting the polyethylene glycol in a suitable size container. The

flutamide was dissolved in the melted polyethylene glycol and the solid dispersion and allowed to solidify” (emphasis added). See, *Stupak*, column 4, lines 16-19.

By contrast, *Lee* teaches that the chewable tablet of the invention prepared by its disclosed process has an advantage in bioavailability resulting from increased absorption rate, because the tablet is “dissolved or chewed in the mouth and then moved into gastrointestinal tract in a state of whole solution or granule, whereas the conventional solid tablet or capsule was absorbed through disintegration and dissolution. Further, the conventional chewable tablet was prepared by mixing a medicament, an effective ingredient, and additives, then melting them at high temperatures as a whole, thus the medicament was liable to change in physico-chemical properties. On the contrary, the medicament contained in the chewable tablet of the present invention as an effective ingredient is not changed in physico-chemical properties and keeps the effect of medicament, therefore has an excellent stability, because the chewable tablet of the present invention is prepared by the process in which the medicament is mixed with a jelly or a chewable base at room temperature” (emphasis added). By distinguishing its chewable tablet, prepared under room temperature conditions, from a melted combination of medicament and additives as taught in *Stupak*, *Lee* is clearly teaching away from the invention taught in *Stupak*. Therefore, one having skill in the art would have no reason to combine these two references to arrive at the present invention.

In the Office Action, Claims 8, 9, 16 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Stupak* in view of U.S. Patent No. 5,126,151 to Bodor (“*Bodor*”). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Applicants submit that the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims. As stated above, *Stupak* fails to disclose or suggest a product comprising a chewable tableted center, wherein the chewable tableted center is not a chewing gum, and a coating comprising a medicament as required, in part, by independent Claims 8 and 16. *Bodor* fails to remedy the deficiencies of *Stupak*, as the Office Action relies on *Bodor* arguably to disclose the medicaments of dependent Claims 9 and 17.

Applicants also submit that the one having skill in the art would have no reason to combine the cited references because the references are directed to two unrelated inventions. *Stupak* is directed to a controlled release solid dosage tablet of flutamide (medicament) that is

designed to provide an immediate release dose and a second delayed dose in pulsatile manner in the gastrointestinal tract for twice a day use. See, *Stupak*, Abstract. More specifically, *Stupak* is directed to a dosage form comprising a core having a medicament (flutamide), an enteric coating surrounding the core, and an immediate release coating applied over the enteric coating, the immediate release coating applied as a dusting powder over the enteric coating. See, *Stupak*, column 1, lines 45-57 and column 3, lines 3-9. By contrast, *Bodor* is directed to a composite delivery system in encapsulated particle form having a U.S. standard mesh size of about 200 to about 30 and preferably about 150 to about 70. See, *Bodor*, column 13, lines 7-9 and Abstract. This encapsulation composition serves to protect materials such as drugs and medicaments and is a component incorporated into various food products, pastes, liquids and baked goods. See, *Bodor*, column 13, lines 7-20. As a result, rather than being directed to anything resembling a dosage tablet or any single product for consumption, *Bodor* is directed to an ingredient of a consumable product. Therefore, one having skill in the art would have no reason to combine these two references to arrive at the present invention.

In summary, Applicants submit that the combination of *Stupak* in view of *Lee* and *Stupak* in view of *Bodor* fails to disclose or suggest every element of the present claims. Moreover, Applicants submit that one having skill in the art would have no reason to combine *Stupak* in view of *Lee* and *Stupak* in view of *Bodor* to arrive at the present invention.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 8-13, 16, 17, 19 and 20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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